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Dated: 10/31/2007

Electronic Signature for James F. Kamp: /James F. Kamp/

Docket No.: 65306-0092
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Timothy A. Becker et al.

Application No.: 10/738,317

Confirmation No.: 8901

Filed: December 17, 2003

Art Unit: 1618

For: COMPOSITIONS AND METHODS FOR
IMPROVED OCCLUSION OF VASCULAR
DEFECTS

Examiner: J. W. Rogers

Mail Stop Amendment
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132

Dear Sir:

I, Timothy A. Becker, Ph.D., being of majority age, hereby state and declare as follows:

1. I am the first named inventor on U.S. Patent Application No. 10/738,317, entitled "COMPOSITIONS AND METHODS FOR IMPROVED OCCLUSION OF VASCULAR DEFECTS," filed 12/17/2003 ("the '317 application").

2. I hold a doctorate degree in Bioengineering from Arizona State University, with my dissertation titled "APPLICATION OF CALCIUM ALGINATE AS AN ENDOVASCULAR EMBOLIZATION MATERIAL FOR VASCULAR LESIONS." After leaving Arizona State University, I joined the University of Michigan – Ann Arbor as a Post-Doctoral Senior Research Associate, where I performed work underlying the present application. I am currently employed as a Product Specialist at WL Gore and Associates – Medical Products Division, Flagstaff, Arizona, pursuing the medical application of my invention.

3. I have carefully reviewed the Final Office Action mailed on May 23, 2007 (the "Office Action"), as well as the cited reference Kipke, U.S. 2001/00331978 ("the Kipke application") and its related issued patent.

4. I am a named inventor in the Kipke application and patent and have personal knowledge of the technology disclosed and discussed in that application, which is based in part on my doctoral work.

5. At page 8 of the Office Action, regarding Claims 33-34 and 36, the Examiner states that "Kipke while disclosing the use of alginates with different guluronic acid and mannuronic acid content is silent on the exact MW of the alginates, although the Examiner concludes that the Kipke application obviously incorporates the same alginates with the same MW because both applications bought the alginates from the same source (Pronova) and apparently used the same commercially available alginates." The Examiner then makes a conclusion of obviousness based on this assumption. As discussed herein, based on my knowledge of the technology disclosed and discussed in the present application and in the Kipke application, the Examiner's assumption is not correct.

6. The alginates discussed in both applications were purchased from the same source, Pronova. However, no characterization of molecular weight was available from the vendor on the batches of alginate used at the time of the Kipke application. The only known characterization was the G-acid content and the purity. Therefore, our optimization of alginates discussed in the Kipke application originally focused on G-acid content and purity only. All testing disclosed in the Kipke application was done with the same batches of alginate. The purified, high G-acid (PHG) batch of alginate was identified as optimal in the Kipke application.


7. Subsequently, when the original batch of PHG alginate was exhausted, a new batch of the PHG-class of alginate was ordered from Pronova. The new PHG batch of alginates was made to the specifications disclosed in the Kipke application. However, the resulting injectable liquid viscosity and final gel strength were significantly different from the original properties disclosed in the Kipke application. The vendor had sent the same class of alginate (PHG), however, the original batch of PHG alginate was no longer available. In addition, although Pronova had begun classifying the new batches of PHG alginates by their molecular weight, this information was not

available for the original batch of PHG alginate. Thus, the MW of the alginate material in the Kipke application is unknown.

8. Without a way to determine the molecular weight of the original material, part of our original work underlying the present application was to characterize the entire range of PHG alginates then currently available from Pronova. In doing so, we discovered the optimal properties of the molecular weight ranges disclosed and claimed in the present application.

9. I further declare that all statements made on my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 10/30/07

Signature: 
Timothy A. Becker, Ph.D.